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MAR 13 2002

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David T. Read  
Acting Director Health Assessment Policy Staff, CDER  
Food and Drug Administration  
1451 Rockville Pike, HFD-7  
Rockville, MD 20852

Dear Mr. Read:

Transmitted herewith is a copy of the application for patent term extension of U.S. Patent No. 5,712,155 (now Reissue Patent No. 36,755) and a copy of the reissued patent. The application was filed on November 22, 2000, under 35 U.S.C. § 156.

The patent claims a product that was subject to regulatory review under the Federal Food, Drug and Cosmetic Act. Subject to final review, the subject patent is considered to be eligible for patent term restoration. Thus, a determination by your office of the applicable regulatory review period is necessary. Accordingly, notice and a copy of the application are provided pursuant to 35 U.S.C. § 156(d)(2)(A).

The original patent included claims

Inquiries regarding this communication should be directed to the undersigned at (703) 306-3159 (telephone) or (703)872-9411 (facsimile).



Karin Tyson  
Senior Legal Advisor  
Office of Patent Legal Administration  
Office of the Deputy Commissioner  
for Patent Examination Policy

cc: Michael A. Sanzo  
Vinson & Elkins  
1455 Pennsylvania Ave. NW  
Washington DC 20004

FDA Docket No. 99E-1086  
Reissue Patent No. 36,755  
Re. ENBREL

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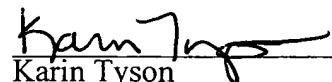
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David T. Read  
Acting Director Regulatory Policy Staff, CDER  
Food and Drug Administration  
1451 Rockville Pike, HFD-7  
Rockville, MD 20852

Dear Mr. Read:

Transmitted herewith is a copy of U.S. Patent No. Re. RE 36,755. Please use this patent number instead of U.S. Patent No. 5,712,155 in connection with the application for patent term extension for the human biological product ENBREL®, which was filed on December 22, 1998, FDA Docket No. 99E-1086.

Telephone inquiries regarding this matter should be directed to the undersigned at (703)306-3159.

  
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Karin Tyson  
Senior Legal Advisor  
Office of Patent Legal Administration  
Office of the Deputy Commissioner for Patent Examination Policy

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Vinson & Elkins  
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